Lab Director Approval: Mark Tolbert / 08/19/2021

QA Manager Approval: Jeffrey Moore / 08/19/2021

Standard Operating Procedure for Corrective Actions

Access to this SOP shall be available within the laboratory for reference purposes; the official copy of this SOP resides on the official Georgia EPD website at https://epd.georgia.gov/about-us/epd-laboratory-operations. Printed copies of this SOP will contain a watermark indicating the copy is an uncontrolled copy.

1. Purpose

1.1. This SOP describes the Georgia Environmental Protection Division Laboratory (Laboratory) procedure and documentation, and

1.2. the requirements for documenting deviations from standard laboratory procedures using Corrective Actions.

1.3. This SOP also provides guidance for completing forms, and noting Corrective Actions in reported data.

2. Scope and Application

2.1. This procedure details the requirements for identifying the need for a Corrective Action, and the initiation, documentation, approval and reporting processes for Corrective Actions.

2.2. Corrective Actions are initiated for any deviation from "normal laboratory activities", i.e. a nonconformance issue. This includes method/SOP deviations, analyst or laboratory errors, facility issues which affect the analysis of samples, etc.

2.3. Corrective Actions may also be initiated as a Preventative Action whenever a situation is identified that has the potential to result in a nonconformance situation if not addressed.

3. Summary

3.1. A Corrective Action may be initiated when any system or situation is determined to be out of control (non-compliant) or has the potential to result in an out of control situation. The initiator may recommend a resolution to the non-compliant situation.

3.2. A Corrective Action may be initiated by any member of the Laboratory staff.

3.3. The Corrective Action then undergoes a cycle of approvals and resolution implementation until a final resolution has been completed and approved by the proper authority.

4. Definitions

4.1. Corrective Action Form (CAF) – A form used to document the nonconformance, suggested and actual resolution(s) and required approvals.

4.2. Initiator – The individual observing and reporting the nonconformance condition.

4.3. Nonconformance – A lack of compliance with a specified process or procedure, quality control criteria, or an issue that has an impact on data quality, or the ability to produce quality data in a timely manner.

4.4. Manual Entry –  indicates the need to manually enter information.

4.5. Keyboard Entry –  indicates electronic entry is expected (preferred for readability, but not required).

5. Personnel Qualifications and Responsibilities

5.1. Any member of the Laboratory staff may initiate a Corrective Action and, in most instances, recommend a resolution.

5.2. Various approvals may only be performed by persons of the specified level (or higher), i.e. Supervisors, Laboratory Managers, and the QA Manager or designate as appropriate.

6. Procedure

6.1. If a staff member observes a nonconformance issue condition, that person will initiate a Corrective Action and generate a Corrective Action Form (CAF).

6.2. Each CAF is assigned a unique ID number. That number should be included on any paperwork affected by the non-conformance issue and in any Labworks comments made concerning the non-conformance. See reference 9.5 this document, “Standard Operating Procedure for Data Comments” for more information on Labworks comments.

6.3. Sequence of Events

6.3.1. Any member of the Laboratory staff may identify a nonconformance situation and initiate a Corrective Action.

6.3.2. The initiator opens the appropriate template (chemistry or microbiology) listed in Section 6.4.2 this document.

6.3.3. The initiator fills in the fields indicated with  as indicated in Section 6.4 this document.

6.3.4. The initiator prints the CAF, initials and dates the CAF in the appropriate fields at the top of page 1.

6.3.4.1. **NOTE: Ensure that the printer is set to 2-sided (duplex) printing.**

6.3.5. The initiator adds the page to the Corrective Action Log for his/her Lab Unit and completes the ID# with the appropriate page number of the log. Note: the ID# appears at least twice on the CAF. If there are attachments, the ID# must be completed on these as well.

6.3.5.1. The log number pages are started at zero each year and numbered sequentially through the year. In the example from Section 6.5.2.4 below, if the last page number is the Inorganic unit Corrective Action Logbook is page 176, the new CAF would be numbered 177 for a completed ID# of 3-061511-177.

6.3.6. The initiator takes the log book to an appropriate Supervisor or Manager for approval to proceed with the recommended resolution.

6.3.6.1. If a CAF is printed on more than one page, or has attachments, all pages should be stapled together before the CAF is added to the log book.

6.3.6.2. If a Supervisor or Manager fills out a CAF for another staff member, the person reporting the non-compliance issue to the Supervisor/Manager is the initiator of the Corrective Action and must initial and date the form as the initiator and person performing the resolutions. The Supervisor/Manager creating the new CAF must initial and date the form beside the area indicated for the initiator at the top of page one of the form.

6.3.6.3. If a Supervisor or Manager fills out a CAF for another staff member, it is the responsibility of that staff member to review all entries performed for that person for accuracy and completeness before initialing and dating the form.

6.3.7. The Supervisor or Manager conducting this first review/approval reviews the CAF for completeness and clarity. The description of the problem, the criteria failed and the recommended resolution should be clearly stated and all appropriate checkboxes checked. CAFs with incomplete information at this point should be rejected. The reviewer should make comments when appropriate modifying the resolution steps to be undertaken.

6.3.8. Any Corrective Actions that are initiated for issues other than failed sample or batch quality control should be submitted to either the QA Manager or the Lab Director for review. A resolution should be decided at that time.

6.3.9. After approval, the initiator should make a photocopy of the CAF to include with the appropriate data package(s).

6.3.10. Upon completing the resolution(s) listed on the CAF, the initiator completes Section 4 of the original CAF and submits it to the appropriate Supervisor or Manager for final approval of the actions taken.

6.3.11. It is the responsibility of the person reviewing the completed resolution to determine that the resolution is indeed complete and that all appropriate documentation concerning the resolution(s) has been completed. This includes

checking Labworks comments for completeness and correctness, deleting unused test codes, etc.

6.3.11.1. Alternately, the reviewer may temporarily approve the resolution(s) by initialing and dating within the comments area of Section 4. During a later review of the data for the affected tests, the reviewer initials and dates the provided fields to indicate that a full review of the problem/resolution has been completed.

6.3.11.2. Regardless of the approach used, all Supervisors and Managers will review the Corrective Action Logs at least once per week (more often if practical). This review is to determine:

6.3.11.2.1. If there are any lingering CAFs that should be addressed.

6.3.11.2.2. If the Laboratory Manager or the QA Manager have added any comments to CAFs indicating further actions that need to be taken by the initiator or primary Supervisor.

6.3.12. Once per week, the Laboratory Manager will review their Lab Unit's Corrective Action Log and approve or comment on changes needed for any open CAFs.

6.3.12.1. The Manager should randomly check CAFs (at least 10% of all CAFs) for completeness and correctness of associated data and comments in Labworks. Such checks should include but are not limited to:

6.3.12.1.1. Checking the comments for appropriate format and complete and correct information.

6.3.12.1.2. Checking to make sure that unused test codes have been deleted.

6.3.12.1.3. Checking validation test codes and statuses.

6.3.12.1.4. Making sure that out of compliance results are properly handled in Labworks (for example, and out of compliance LCS recovery result should be recognized and flagged in red by Labworks).

6.3.12.2. If the Manager approves of the CAF, they will complete Section 5 by initialing and dating the appropriate fields.

6.4. <u>The Corrective Action Form (CAF)</u>

6.4.1. There are two versions of the CAF; one for Chemistry and one for Microbiology. The forms are very similar and are used the same way. The examples in this document are taken from the Chemistry version. There are two identical copies of the Chemistry version to allow for the frequent use of this form by several lab units.

6.4.2. The CAF is a Microsoft Office Template file with a .docx extension. The files are located on the shared data drive (the "S:" drive for most users) as:

6.4.2.1. S:\Approved Forms\Corrective Action Form Chemistry Form 9.1 Rev. 2.docx.

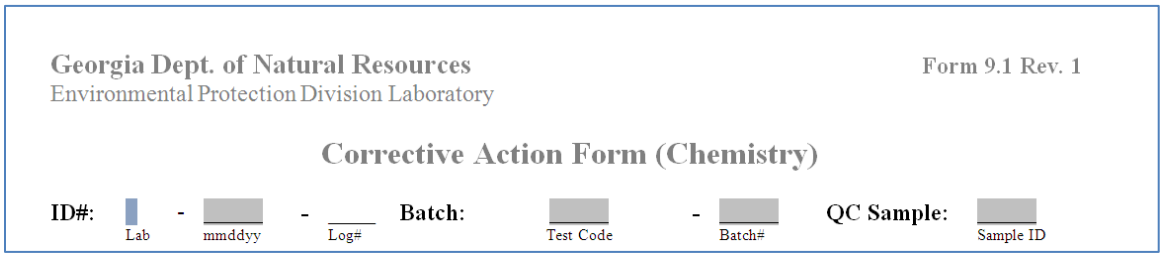
6.4.2.2. S:\ Approved Forms\Corrective Action Form Micro Form 9.2 Rev. 1.docx.

6.4.3. The initiator opens the appropriate CAF template. The form will open with the cursor in the first field in which information is to be entered.

6.4.4. Information is entered in each field then the user may use the "Tab" key to move the cursor to the next field. Another field may also be selected using the computer mouse.

6.5. *Corrective Action Form (CAF) Fields*

6.5.1. The topmost section of the form is used to assign a unique identifier to the CAF as well as indicate specific batch information when appropriate.


Georgia Dept. of Natural Resources
Environmental Protection Division Laboratory
Form 9.1 Rev. 1
Corrective Action Form (Chemistry)
ID#: Lab - mmddyy - Log# Batch: Test Code - Batch# QC Sample: Sample ID

6.5.2. ID# - The CAF unique identifier is entered into the "ID#" area. The ID# consists of three parts, the Lab #, the current date ("mmddyy") and the "Log#".

6.5.2.1. The Lab# is determined from Table 6.1 below:

Table 6.1 – Laboratory Unit Numbers

Lab #	Lab Unit
1	Organic
2	Metals
3	Inorganic
4	Air
5	Micro
6	Admin
7	GC/MS
8	Crypto

6.5.2.2. The appropriate number from Table 6.1 in the Lab # field.

6.5.2.3. The date portion is entered as numbers "mmddyy" with mm = the 2-digit month, dd = the 2-digit day and yy = the 2-digit year. For example, June 15, 2011 would be entered as 061511.

6.5.2.4. At this point, a unique ID# would be partially completed. If the example date above were for a CAF being generated for the Inorganic Lab, the partial ID# would look like this: **ID#:** 3-061511-_____.

6.5.2.5. The Log# is manually entered after the form as been printed. See Sections 6.3.4 – 6.3.5.1.

6.5.3. Batch ID - The "Batch ID" consists of two parts, the Labworks test code and the actual batch number that Labworks assigns to a QC batch. If the Corrective

Action does not concern a QC batch, enter "NA" in the Test Code and Batch# fields.

6.5.3.1. The Test Code is the Labworks test code under which the samples in question were batched. The test code must be entered exactly as it is used in the batch name (Batch ID) so that those reviewing the CAF later can search for the batch in Labworks.

6.5.3.2. The Batch# is the numeric part of the batch name assigned by Labworks. Always double check this entry to make sure that it is correct.

6.5.4. QC Sample – The "QC Sample" is the sample associated with this batch in Labworks as the QC Sample. Some batches have QC test attached to more than one sample, but only one sample in a batch is assigned as the QC Sample in Labworks. If the Corrective Action does not concern a QC batch, enter "NA" in the QC Sample field even if there is an un-batched sample(s) involved.

6.5.5. Initiated by (Initials – Date) - These fields are completed immediately after printing the form. See Section 6.3.4 – 6.3.5.1 this document.

6.5.6. The next sections of the form, Sections 1a, 1b and the choices above them, are used to describe the nonconformance issue that prompted the Corrective Action.

Check all that apply: ☐ LCS/LCSD Recovery ☐ LCSD Precision ☐ MS/MSD Recovery ☐ MSD Precision ☐ Method/Other Blank(s) ☐ Internal Standard ☐ Surrogate Recovery ☐ Calibration Criteria ☐ Calibration Verification ☐ Other

1a.) Description of Problem(s): ☐ Attachments ☐ Additional Info (Section 7)	**1b.) Criteria:** ☐ NA

6.5.6.1. A CAF may address more than one nonconformance condition. Check all that apply and/or enter a short (one or two word) description of a nonconformance in "Other". If more than one issue is to be listed, enter a number for each before each checkbox that is associated with a numbered nonconformance (see Section 6.5.6.3. this document).

6.5.6.2. Check "Attachments" if there will be additional pages attached to the CAF.

6.5.6.2.1. If additional pages are attached to a CAF, the CAF ID number should appear on the first page of the attachment, at a minimum. Each page of the attachment is number "Page X of Y" where "X" is the current page number and "Y" is the total number of pages. If the software used to print the attachment numbers the pages, it is not necessary to add "Page X of Y" numbering. If the pages are not uniquely

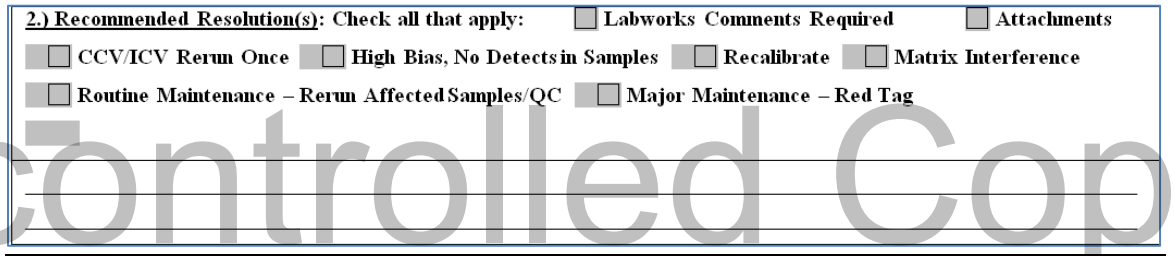
identified, each page must have the CAF ID number noted. The additional pages should be stapled to the CAF.

6.5.6.3. Section 1a - Enter a description of the nonconformance in the field provided. If more than one issue is begin addressed in the CAF, number each one and place on a separate line. The field will accept line feeds (new lines created with the "Enter" key).

6.5.6.4. If more space is needed, check the "Additional Info (Section 7)" checkbox and use Section 7 of the form to continue.

6.5.6.5. Section 1b – Enter the criteria that each nonconformance failed, numbering to match the nonconformance items. If there are no criteria associated with the nonconformance items, check "NA".

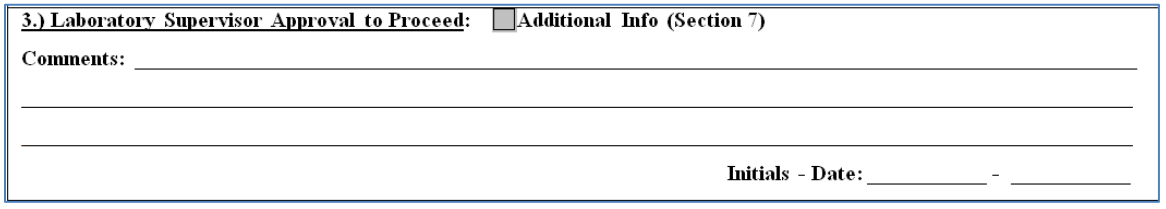
6.5.7. Section 2, "Recommended Resolution(s)" is used by the initiator to suggest activities to resolve the issue(s) listed in Section 1a of the CAF.



6.5.7.1. The selections for "Labworks Comments Required" and "Attachments" are intended to be general descriptions; the remaining resolution checkboxes may be numbered to match the items from Section 1a.

6.5.7.1.1. The texts of the resolution checkboxes may be sufficient to describe a suggested resolution. If so, no further input is required for that resolution.

6.5.8. Section 3, "Laboratory Supervisor Approval to Proceed" – This section is used by a Supervisor or Manager in the same Lab Unit as the initiator to approve the suggested resolution(s). There are lines provided for that person to enter comments concerning the suggested action(s).



6.5.9. Section 4, "Resolution Completed" – This section is used by the primary Supervisor of the affected analysis, or the initiator's immediate Supervisor for other issues, to approve the completed resolution(s).

4.) ☐ Resolution Completed: ☐ Additional Info (Section 7)

Comments/Resolution Outcome: _____

_____

_____

_____

Analyst's Initials - Date _____ - _____ **Primary Supervisor's Initials – Date** _____ - _____

The initiator checks the "Resolution Completed" checkbox, and possibly the "Additional Info (Section 7)" checkbox if appropriate, and fills in the "Analyst's Initials – Date" fields of Section 4 of the CAF. The primary Supervisor for the analytical method, the initiator's immediate Supervisor (preferred) for other issues or the Lab Unit Manager reviews, comments and approves by initialing and dating where appropriate in Section 4 of the CAF. Follow-up activities to resolve issues must be provided in this section.

6.5.10. Section 5, "Laboratory Manager Review" – This section is for the Lab Unit Manager to review and approve a CAF with a completed resolution.

5.) Laboratory Manager Review:

Initials - Date: _____ - _____

Comments: _____

_____

6.5.11. Section 6, "QA Manager or Lab Director Review" - This section is for the QA Manager or Lab Director to review and approve a CAF with a completed resolution and Lab Manager's approval.

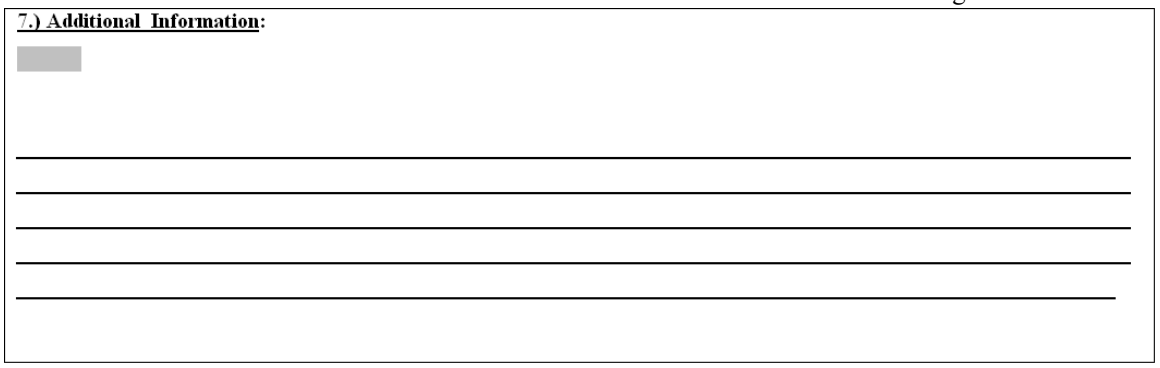
6.) QA Manager or Lab Director Review (If Required)

Initials – Date:_____-_____

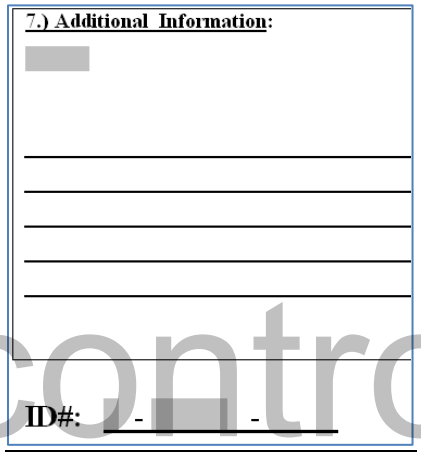
Comments:_____

_____

6.5.12. Section 7, "Additional Information" – This section has a field that the initiator can fill with additional information before printing. There is also space for hand written information to be entered by the initiator or the reviewing Supervisors or Managers.



6.5.13. ID# - The CAF unique identifier that was entered into the "ID#" area at the top of the first page of the form is repeated here.



7. Criteria

7.1. This document is based, in part, on information found in references 9.1 and 9.2 this document.

8. Records Management

8.1. The most recent Corrective Action Forms are maintained in each Lab Unit in a maroon 3-ring binder labeled for that purpose.

8.2. CAFs removed from the binder for archiving must be kept on site for at least three years.

8.3. After three years, archived CAFs may be stored off site.

8.3.1. Admin and Metals CAFs must be archived for a total of 12 years (Lead-Copper Rule).

8.3.2. Organic, Inorganic, GC/MS and Micro CAFs must be archived for a total of 10 years (Drinking Water Program).

8.3.3. Air CAFs must be archived for seven years (Ambient Air Monitoring Program).

8.4. A copy of a CAF associated with any sample(s) in a data packet must be included in the data packet. At a minimum, the copy included must be completed through Section 4 of the CAF.

9. References

9.1. "Laboratory Operations and Quality Assurance Manual" US EPA, SESD, Region 4, 2011.

9.2. "Control of Non-Conforming Work", US FDA, ORA, ORA-LAB.4.9, Version 1.2, 10/01/2003.

9.3. Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water – US EPA – EPA 815-F-08-006- January 2005.

9.4. Georgia EPD Laboratory Quality Assurance Plan, most recent revision.

9.5. "Standard Operating Procedure for Data Comments" Georgia EPD Laboratory SOP 6-055 online revision.

10. Attachments and Appendices

10.1. Appendix A : Corrective Action Form (Chemistry) – Corrective Action Form (Chemistry), Form 9.1 Rev. 2.

10.2. Appendix B : Corrective Action Form (Microbiology) – Corrective Action Form (Microbiology), Form 9.2 Rev. 1.

Appendix A : Corrective Action Form (Chemistry)

Georgia Dept. of Natural Resources **Form 9.1 Rev. 2**
Environmental Protection Division Laboratory

Corrective Action Form (Chemistry)

ID#: - _____ - _____ **Batch:** _____ - _____ **QC Sample:** _____
Lab mmddyy Log# Test Code Batch# Sample ID

Initiated by (Initials - Date): _____ - _____

Check all that apply: ☐ LCS/LCSD Recovery ☐ LCSD Precision ☐ MS/MSD Recovery ☐ MSD Precision
☐ Method/Other Blank(s) ☐ Internal Standard ☐ Surrogate Recovery
☐ Calibration Criteria ☐ Calibration Verification ☐ Other

1a.) Description of Problem(s): ☐Attachments ☐Additional Info (Section 7)	1b.) Criteria: ☐NA

2.) Recommended Resolution(s): Check all that apply: ☐ Labworks Comments Required ☐ Attachments
☐ CCV/ICV Rerun Once ☐ High Bias, No Detects in Samples ☐ Recalibrate ☐ Matrix Interference
☐ Routine Maintenance – Rerun Affected Samples/QC ☐ Major Maintenance – Red Tag

3.) Laboratory Supervisor Approval to Proceed: ☐Additional Info (Section 7)
Comments: _____

Initials - Date: _____ - _____

4.) ☐ Resolution Completed: ☐Additional Info (Section 7)
Comments/Resolution Outcome: _____

Analyst's Initials - Date _____ - _____ **Primary Supervisor's Initials – Date** _____ - _____

5.) Laboratory Manager Review:	6.) QA Manager or Lab Director Review (If Required):
Initials - Date: _____ - _____	Initials - Date: _____ - _____
Comments: _____	Comments: _____

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Form 9.1 Rev. 2

Corrective Action Form (Chemistry)

7.) Additional Information:

ID#: __-_____-_____

Appendix B : Corrective Action Form (Microbiology)

Georgia Dept. of Natural Resources **Form 9.2 Rev. 1**
Environmental Protection Division Laboratory

Corrective Action Form (Microbiology)

ID#: - _____ - _____ **Batch:** _____ - _____ **QC Sample:** _____
Lab mmddyy Log# Test Code Batch# Sample ID

Initiated by (Initials - Date): _____ - _____

Check all that apply:

- ☐ Positive Control (MS)
- ☐ Negative Control (Method Blank)
- ☐ Duplicate (MSD) Precision
- ☐ LCS (OPR) Recovery
- ☐ Holding Time
- ☐ Receipt Temperature
- ☐ Data Entry Error
- ☐ Other

1a.) Description of Problem(s): ☐ Attachments

1b.) Criteria: ☐ NA

2.) Recommended Resolution(s): Check all that apply: ☐ Labworks Comments Required ☐ Attachments

- ☐ Pos. & Neg. Controls Passed – Use Results
- ☐ Request Sample Recollection
- ☐ Matrix Interference
- ☐ Routine Maintenance
- ☐ Major Maintenance – Red Tag
- ☐ No Samples Affected

3.) Laboratory Supervisor Approval to Proceed:

Comments: _____

Initials - Date: _____ - _____

4.) ☐ Resolution Completed:

Comments/Resolution Outcome: _____

Analyst's Initials - Date _____ - _____ Primary Supervisor's Initials – Date _____ - _____

5.) Laboratory Manager Review:

Initials - Date: _____ - _____

Comments: _____

6.) QA Manager or Lab Director Review (If Required):

Initials - Date: _____ - _____

Comments: _____

Georgia Dept. of Natural Resources **Form 9.2 Rev. 0**
Environmental Protection Division Laboratory

Corrective Action Form (Microbiology)

7.) Additional Information:

ID#: __-____-____